K061390

JUL - 5 2006

510(k) Summary for the
Dimension Vista™ System Enzyme 2 Calibrator
(ENZ 2 CAL – KC320)

A. 510(k) Number:

B. Analytes: Alanine aminotransferase (ALT) and aspartate aminotransferase (AST)

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Contact: Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ Enzyme 2 Calibrator
(ENZ 2 Cal – KC320)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: JIX – Calibrator, Multi-Analyte Mixture
4. Panel: Clinical Chemistry

G. Intended Use: The Enzyme 2 Calibrator is an *in vitro* diagnostic product for the calibration of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) on the Dimension Vista™ System.

H. Device Description:

The Enzyme 2 Calibrator is a liquid, multi-analyte, bovine serum albumin based product containing alanine aminotransferase (ALT) and aspartate aminotransferase (AST) from porcine heart.
The kit consists of six vials, three vials of Calibrator A and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 1.5 mL.

I. Substantial Equivalence Information:

1. Predicate Device: Dimension® Enzyme Verifier (DC19).
2. Predicate K Number: K860021 for Dimension® clinical chemistry system.
3. Comparison with Predicate:

Item	Dimension Vista™ Enzyme 2 Calibrator	Dimension® Enzyme Verifier
Intended Use	The Enzyme 2 Calibrator is an *in vitro* diagnostic product for the calibration of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) on the Dimension Vista™ System.	Enzyme Verifier is an *in vitro* diagnostic product to be used to verify alkaline phosphatase (ALP), amylase (AMY), g-glutamyl transferase (GGT), aspartame aminotransferase (AST), alanine aminotransferase (ALT) and lactic dehydrogenase (LDH) method performance on the Dimension® clinical chemistry system.
Analytes	Alanine aminotransferase (ALT) Aspartate aminotransferase (AST)	Alkaline phosphatase (ALP), Amylase (AMY) g-glutamyl transferase (GGT), Aspartame aminotransferase (AST), Alanine aminotransferase (ALT), Lactic dehydrogenase (LDH)
Form	Liquid	Lyophilized
Traceability	ALT/AST Master Pool, Dimension® clinical chemistry system values.	ALT/AST Master Pool, Dimension® clinical chemistry system values.
Matrix	Bovine serum and porcine heart based product.	Human serum and porcine heart based product
Levels	Two calibration levels	Three verification levels

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
   Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
   ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. Stability: Calibrator shelf life for the Dimension Vista™ Enzyme 2 Calibrator is determined to be 12 months. Calibrator shelf life is determined by comparing results of the product stored at 4°C with control stored at -70°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the

calibration. Recovery versus time is monitored and percent change over time is determined where the allowable shelf life percent change should be ≤ 5 %. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.
A vial that is punctured (opened) by the instrument and stored on board has a seven day stability claim.
An vial that is uncapped, recapped and stored in a refrigerator, not on instrument, has a stability claim of 31 days.

Both opened and punctured vials are tested on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 1, 8, 15, 22, and 32 versus freshly opened vials.

2. Traceability: The assigned values of the Enzyme 2 Calibrator are standardized to a master pool that is assigned by the Dimension® clinical chemistry system.

3. Value Assignment:

To manufacture a calibrator lot, calculated quantities of a verified stock solution are added to a bovine serum albumin base at target concentrations. The concentration of each level is verified on an instrument calibrated with an approved Master Pool. The Master Pool values are assigned for each level on multiple Dimension® instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 5 2006

Mr. Victor M. Carrio
RA/QS Compliance Manager
Dade Behring, Inc.
500 GBC Drive
PO Box 6101, Mailstop 514
Newark, DE 19714-6101

Re: k061390
Trade/Device Name: Dimension Vista™ Enzyme 2 Calibrator
(AST/ALT Calibrator-KC320)
Regulation Number: 21 CFR§ 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: May 17, 2006
Received: May 18, 2006

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K061390

Device Name:

Dimension Vista™ Enzyme 2 Calibrator (AST/ALT Calibrator , KC320)

Indications for Use:

The Enzyme 2 Calibrator is an *in vitro* diagnostic product for the calibration of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) on the Dimension Vista™ System.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K061390